Exhibit 300: Capital Asset Plan and Business Case Summary Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview

1. Date of Submission: 2011-02-28

2. Agency: 009

3. Bureau: 10

4. Name of this Investment: FDA Operational Infrastructure

5. Unique Project (Investment) Identifier (UPI): 009-10-02-00-01-7031-00

- 6. What kind of investment will this be in FY 2012?: Operations and Maintenance
 - Planning
 - Full Acquisition
 - Operations and Maintenance
 - Mixed Life Cycle
 - Multi-Agency Collaboration
- 7. What was the first budget year this investment was submitted to OMB? FY2004

8.

a. Provide a brief summary of the investment and justification, including a brief description of how this closes in part or in whole an identified agency performance gap, specific accomplishments expected by the budget year and the related benefit to the mission, and the primary beneficiary(ies) of the investment.

This investment supports the PMA EGov initiative by providing IT infrastructure support and services through electronic delivery mechanisms (Internet, e-business tools) which enable business operations. It also supports the HHS goals of effective management of IT and advancing scientific and biomedical research and development related to health and human services through information delivery: internally, to state and local governments, medical industry, scientific communities, and the public. It also serves to transport and leverage delivery of HHS regulatory activities. Stakeholders rely on FDA for the safety of regulated products. Prior to FY2004, the FDA IT infrastructure was managed in a decentralized manner based on the needs and work environment of the Centers (with the exception of Telecom & WAN). This made it difficult to effect change in strategic direction, policy development or benefit from gains in efficiency in process, acquisition, standards development, and managing maintenance costs. This investment represents the decision to provide a portfolio of services to 12,000 staff via a consolidated infrastructure shared services model framed by a performance based Service Level Agreement (SLA). The services include: server management, telecommunications & network; Customer Care & a consolidated IT Helpdesk with on-site support; Applied Engineering: ensures successful systems integration & security operations; Strategic Projects - customer relationship management, planning/project management, & training efforts; Internet/Intranet Infrastructure management; & White Oak Data Center Consolidation. This selected approach continues to correct inefficiencies of a decentralized model while reinvesting savings into quality improvement activities including risk management.

 b. Provide any links to relevant websites that would be useful to gain additional information on the investment including links to GAO and IG reports.

Title

Link

FDA Needs to Establish Key Plans and Processes for System Modernization Efforts http://www.gao.gov/products/GAO-09-523

9.

- a. Provide the date of the Agency's Executive/Investment Committee approval of this investment. 2008-07-21
- b. Provide the date of the most recent or planned approved project charter. 2007-06-06
- 10. Contact information?
 - a. Program/Project Manager Name: *

Phone Number: *

Email: *

b. Business Function Owner Name (i.e. Executive Agent or Investment Owner): Albaugh, Joe Phone Number: *

Email: *

- 11. What project management qualifications does the Project Manager have? (choose only one per FAC-P/PM or DAWIA): Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
 - Project manager has been validated according to FAC-P/PM or DAWIA criteria as qualified for this investment.
 - Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
 - Project manager assigned to investment, but does not meet requirements according to FAC-P/PM or DAWIA criteria.
 - Project manager assigned but qualification status review has not yet started.
 - No project manager has yet been assigned to this investment.

Section B: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.B.1: Summary of Funding
(In millions of dollars)
(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)

(Estimates for 61+1 and beyond are for planning purposes only and do not represent budget decisions)											
	PY-1 and earlier	PY 2010	CY 2011 (CY Continuing Resolution)	BY 2012	BY+1 2013	BY+2 2014	BY+3 2015	BY+4 and beyond	Total		
Planning:	*	*	*	*	*	*	*	*	*		
Acquisition:	*	*	*	*	*	*	*	*	*		
Planning & Acquisition Government FTE Costs	*	*	*	*	*	*	*	*	*		
Subtotal Planning & Acquisition(DME):	*	*	*	*	*	*	*	*	*		
Operations & Maintenance:	*	*	*	*	*	*	*	*	*		
Disposition Costs (optional):	*	*	*	*	*	*	*	*	*		
Operations, Maintenance, Disposition Government FTE Costs	*	*	*	*	*	*	*	*	*		
Subtotal O&M and Disposition Costs (SS):	*	*	*	*	*	*	*	*	*		
TOTAL FTE Costs	*	*	*	*	*	*	*	*	*		
TOTAL (not including FTE costs):	*	*	*	*	*	*	*	*	*		
TOTAL (including FTE costs):	*	*	*	*	*	*	*	*	*		
Number of FTE represented by	*	*	*	*	*	*	*	*	*		

Table I.B.1: Summary of Funding (In millions of dollars) (Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)												
	PY-1 and earlier	PY 2010	CY 2011 (CY Continuing Resolution)	BY 2012	BY+1 2013	BY+2 2014	BY+3 2015	BY+4 and beyond	Total			
Costs:												

- 2. Insert the number of years covered in the column "PY-1 and earlier":
- 3. Insert the number of years covered in the column "BY+4 and beyond": *
- 4. If the summary of funding has changed from the FY 2011 President's Budget request, briefly explain those changes:

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Section C: Acquisition/Contract Strategy (All Capital Assets)

1.

1 -					Table	0.4.0	ete Teble						
						C.1 Contra	cts lable						
Contract Status	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	Solicitation ID	Alternativ e financing	EVM Require d	Ultimate Contract Value (M)	Type of Contract/Ta sk Order (Pricing)	Is the contract a Perform ance Based Service Acquisit ion (PBSA)?	Effective date	Actual or expected End Date of Contract/Ta sk Order	Extent Competed	Short description of acquisition
Awarded		HHSF223200750424 W			*	*	\$8.0	Firm Fixed Price	Y	2007-11-22	2012-06-30		Lease of servers and other equipment for Field Offices
Awarded		HHSF223200650725 G			*	*	\$0.7	Time and Materials	Y	2006-09-27	2008-09-30		
Awarded		HHSF223200750682 G			*	*	\$1.0	Time and Materials	Υ	2007-09-24	2008-09-19		
Awarded		HHSF223045500			*	*	\$44.0	Fixed Price Incentive	Y	2004-10-01	2009-09-30		
Awarded		HHSF22320075036 2P			*	*	\$0.5	Other (none of the above)	N	2007-09-14	2009-05-18	N	CONTRACT WILL PROVIDE TECHNICAL SUPPORT TO FDA TELECOM LOCAL AND FIELD OFFICES

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	Table I.C.1 Contracts Table												
Contract Status	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	Solicitation ID	Alternativ e financing	EVM Require d	Ultimate Contract Value (M)	Type of Contract/Ta sk Order (Pricing)	Is the contract a Perform ance Based Service Acquisit ion (PBSA)?	Effective date	Actual or expected End Date of Contract/Ta sk Order	Extent Competed	Short description of acquisition
Awarded		HHSF22320055000 0I			*	*	\$3.0	Labor Hours	N	2005-02-28		N	IT SERVICES
Awarded		HHSF22320085001 41			*	*	\$346.0	Cost Plus Fixed Fee	Υ	2008-09-29		Y	ICT21 PROGRAM IDIQ CONTRACT

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:

3.

- a. Has an Acquisition Plan been developed? If yes, please answer the questions that follow *
- b. Does the Acquisition Plan reflect the requirements of FAR Subpart 7.1 *
- c. Was the Acquisition Plan approved in accordance with agency requirements *
- d.lf "yes," enter the date of approval? *
- e.ls the acquisition plan consistent with your agency Strategic Sustainability Performance Plan? *
- f. Does the acquisition plan meet the requirements of EOs 13423 and 13514? *
- g.If an Acquisition Plan has not been developed, provide a brief explanation.

Part II: IT Capital Investments

Section A: General

- 1.
- a. Confirm that the IT Program/Project manager has the following competencies: configuration management, data management, information management, information resources strategy and planning, information systems/network security, IT architecture, IT performance assessment, infrastructure design, systems integration, systems life cycle, technology awareness, and capital planning and investment control. yes
- b.If not, confirm that the PM has a development plan to achieve competencies either by direct experience or education.
- 2. Describe the progress of evaluating cloud computing alternatives for service delivery to support this investment.
- 3. Provide the date of the most recent or planned Quality Assurance Plan
- 4.
- a. Provide the UPI of all other investments that have a significant dependency on the successful implementation of this investment.
- b. If this investment is significantly dependent on the successful implementation of another investment(s), please provide the UPI(s).
- 5. An Alternatives Analysis must be conducted for all Major Investments with Planning and Acquisition (DME) activities and evaluate the costs and benefits of at least three alternatives and the status quo. The details of the analysis must be available to OMB upon request. Provide the date of the most recent or planned alternatives analysis for this investment. 2004-02-23
- 6. Risks must be actively managed throughout the lifecycle of the investment. The Risk Management Plan and risk register must be available to OMB upon request. Provide the date that the risk register was last updated.

Section B: Cost and Schedule Performance

	Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:											
Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete		
Infrastructure Operations and Maintenance (FY2008)	SS	*	\$109.8	\$109.8	2007-10-01	2007-10-01	2008-09-30	2008-09-30	100.00%	100.00%		
Infrastructure Operations and Maintenance (FY2009)	SS	*	\$129.1	\$129.1	2008-10-01	2008-10-01	2009-09-30	2009-09-30	100.00%	100.00%		
ITI Program Management and Planning (FY2010)	SS	*	\$16.0	\$7.7	2009-10-01		2010-09-30		41.67%	41.67%		
Infrastructure Operations and Maintenance (FY2010)	SS	*	\$134.9	\$30.7	2009-10-01		2010-09-30		41.67%	41.67%		
ITI Program Management and Planning (FY2011)	SS	*	\$16.5		2010-10-01		2011-09-30		0.00%	0.00%		
Infrastructure Operations and Maintenance (FY2011)	SS	*	\$139.5		2010-10-01		2011-09-30		0.00%	0.00%		
ITI Program Management and Planning (FY2012)	SS	*	\$17.0		2011-10-01		2012-09-30		0.00%	0.00%		
Infrastructure Operations and Maintenance (FY2012)	SS	*	\$144.3		2011-10-01		2012-09-30		0.00%	0.00%		
ITI Program Management and	SS	*	*	*	2012-10-01	*	2013-09-30	*	*	*		

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	Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:											
Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete		
Planning (FY2013)												
Infrastructure Operations and Maintenance (FY2013)	SS	*	*	*	2012-10-01	*	2013-09-30	*	*	*		
ITI Program Management and Planning (FY2014)	SS	*	*	*	2013-10-01	*	2014-09-30	*	*	*		
Infrastructure Operations and Maintenance (FY2014)	SS	*	•	*	2013-10-01	*	2014-09-30	*	*	*		

- 2. If the investment cost, schedule, or performance variances are not within 10 percent of the current baseline, provide a complete analysis of the reasons for the variances, the corrective actions to be taken, and the most likely estimate at completion. Not Applicable
- 3. For mixed lifecycle or operations and maintenance investments an Operational Analysis must be performed annually. Operational analysis may identify the need to redesign or modify an asset by identifying previously undetected faults in design, construction, or installation/integration, highlighting whether actual operation and maintenance costs vary significantly from budgeted costs, or documenting that the asset is failing to meet program requirements. The details of the analysis must be available to OMB upon request. Insert the date of the most recent or planned operational analysis. 2008-05-25
- 4. Did the Operational analysis cover all 4 areas of analysis: Customer Results, Strategic and Business Results, Financial Performance, and Innovation?

Section C: Financial Management Systems

Table II.C.1: Financial Management Systems										
System(s) Name	System acronym	Type of Financial System	BY Funding							

Section D: Multi-Agency Collaboration Oversight (For Multi-Agency Collaborations only) Table II.D.1. Customer Table: **Customer Agency** Joint exhibit approval date NONE **Table II.D.2. Shared Service Providers Shared Service Asset Title** Shared Service Provider Exhibit 53 UPI (BY 2011) **Shared Service Provider (Agency)** Table II.D.3. For IT Investments, Partner Funding Strategies (\$millions): Partner Partner exhibit 53 UPI **BY Monetary** Agency (BY 2012) Fee-for-Service Fee-for-Service NONE Table II.D.4. Legacy Systems Being Replaced Name of the Legacy Date of the System **Current UPI**

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Section E: Performance Information

			Table I.E.1a. Performa	nce Metric Attributes				
Measurement Area (For IT Assets)	Measurement Grouping (For IT Assets)	Measurement Indicator	Reporting Frequency	Unit of Measure	Performance Measure Direction	Baseline	Year Baseline Established for this measure (Origination Date)	
Technology	Availability	% of Availability of Blackberry Messaging Service	quarterly	%	Increase	97% availability Blackberry Messaging Service	2008-09-01	
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated	
		2008	98% availability of Blackberry services (outside of vendor failure or maintenance)	98% availability of Blackberry services (outside of vendor failure or maintenance)	Met	2010-09-16		
				2009	99% availability of Blackberry services (outside of vendor failure or maintenance)	TBD		2010-09-16
				2010	maintain 99% availability of Blackberry services (outside of vendor failure or maintenance)			2010-09-16
			2011	maintain 99% availability of Blackberry services (outside of vendor failure or maintenance)			2010-09-16	
			2012	maintain 99% availability of Blackberry services (outside of vendor failure or maintenance)			2010-09-16	
		2013	maintain 99% availability of Blackberry services (outside of vendor failure or maintenance)			2010-09-16		
		2014	maintain 99% availability of Blackberry services (outside of vendor failure or maintenance)			2010-09-16		

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Processes and Activities	Efficiency	fficiency % of time servers are available	quarterly	%	Increase	89% of time servers are available	2007-09-01						
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated						
			2007	90% of time servers are available	95% server availability	Met	2010-09-16						
			2008	90% of time servers are available	90% of time servers are available	Met	2010-09-16						
			2009	maintain 90% of time servers are available	TBD		2010-09-16						
			2010	maintain 90% of time servers are available	TBD		2010-09-16						
			2011	maintain 90% of time servers are available	TBD		2010-09-16						
			2012	maintain 90% of time servers are available	TBD		2010-09-16						
		se Time % wait time to answer by Tier 1 level support within two minutes	2013	maintain 90% of time servers are available	TBD		2010-09-16						
			2014	maintain 90% of time servers are available	TBD		2010-09-16						
Customer Results	Response Time		quarterly	%	Increase	90% of calls answered in < 2 minutes	2007-09-01						
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated						
									2007	92% of calls in < 2 minutes	95% of calls were answered in < 2 minutes	Met	2010-09-16
			2008	94% of calls in < 2 minutes	94% of calls in < 2 minutes	Met	2010-09-16						
			2009	95% of calls in < 2 minutes	TBD		2010-09-16						

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			2010	maintain 95% of calls in < 2 minutes	TBD		2010-09-16
			2011	maintain 95% of calls in < 2 minutes	TBD		2010-09-16
			2012	maintain 95% of calls in < 2 minutes	TBD		2010-09-16
			2013	maintain 95% of calls in < 2 minutes	TBD		2010-09-16
			2014	maintain 95% of calls in < 2 minutes	TBD		2010-09-16
Mission and Business Results	Higher Education	Average rating of customer satisfaction with course material	annual	#	Increase	4.5 (scale of 1.0-5.0)	2007-09-01
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2007	4.6	4.8	Met	2010-09-16
			2008	4.65	4.65	Met	2010-09-16
			2009	4.7	TBD		2010-09-16
			2010	4.75	TBD		2010-09-16
			2011	4.8	TBD		2010-09-16
			2012	4.8	TBD		2010-09-16
			2013	4.8	TBD		2010-09-16
			2014	4.8	TBD		2010-09-16

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* - Indicates data is redacted.

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